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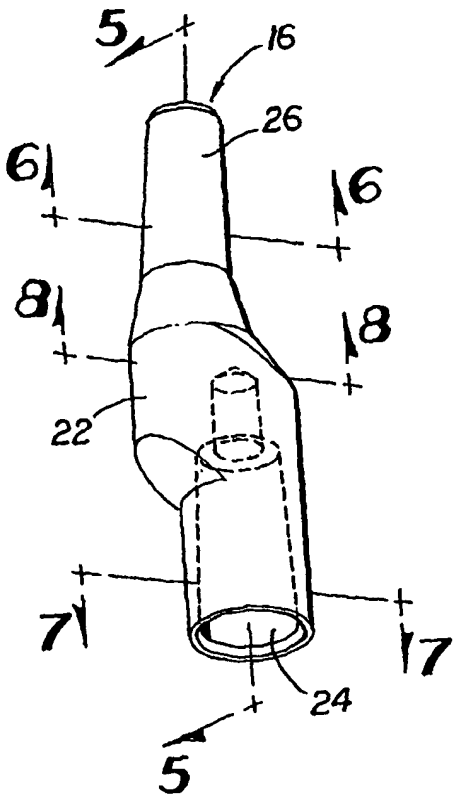
(54) Title: ORTHOPEDIC IMPLANT EXTENSION



(57) Abstract: A stem extension for surgical implants such as tibial or femoral knee implants. The stem extension is interposed between the stem and its load bearing component (i.e., tibial tray or condylar component) and angularly orients the attached stem relative to the load bearing component to facilitate positioning of the stem in the bone canal and alignment of the load bearing component with the mechanical axis of the leg. The extension includes a female taper that engages the load bearing component. The extension also includes a male taper having a longitudinal axis oriented at an angle relative to the longitudinal axis of the female taper. Engagement of the male taper with the stem thereby orients the stem at an angle relative to the longitudinal axis of the load bearing component. Because the bone canal into which the stem is inserted is oftentimes angled relative to the mechanical axis of the leg, such orientation of the stem adjusts for the contour and/or angulation of the canal and facilitates positioning of the stem in the canal in a manner that promotes the desired alignment between the load bearing component and the mechanical axis of the leg, thereby allowing the implant to more closely replicate the geometry of the knee and leg. In addition to being oriented angularly, the female and male taper of the extension may also be offset parallel to facilitate insertion of the stem into canals that are not only angled relative to, but also offset from, the mechanical axis of the leg.

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Orthopedic Implant Extension

Field of the Invention

This invention relates generally to an intermediate stem extension that connects a stem to a tibial and/or femoral load bearing component of a tibial/femoral orthopedic implant. The stem extension has a female taper which engages the tibial and/or femoral load bearing component and a male taper which engages the stem and which is offset from and angled relative to the female taper to orient the stem and thus facilitate reception of the stem in a bowed or angled tibial or femoral canal.

Background of the Invention

Orthopedic implants, such as knee implants, typically include a tibial implant and a femoral implant. The tibial implant generally includes a load bearing component (such as a tibial plate) which may be connected to a stem to be received in the tibial canal to stabilize the load bearing component. The femoral implant includes a load bearing component (such as a condylar component) which is connected to the distal end of the femur. The femoral load bearing component is sometimes connected to a stem which is received in the femoral canal to stabilize the load bearing component.

The tibial plateau and the condyles of the femur bearing on the tibial plateau act similar to a hinge within the knee to allow bending and other movement of the knee. Optimal movement and operation of the knee is achieved when both the tibial plateau and the condyles are aligned with the mechanical axis of the leg (defined as the line from the center of the femoral head to the center of the ankle). The tibial load bearing component and the femoral load bearing component ultimately cooperate with each other to replicate as closely as possible the action and relationship of the tibial plateau and the condyles of the femur bearing on it. Just as with an actual knee, the success of such implants depends at least partially on their positioning within

the knee so that the longitudinal axes of the tibial load bearing component and the femoral load bearing component are aligned with the mechanical axis of the leg.

Very briefly, to implant the tibial and femoral implants into the knee, the surgeon first reams the intramedullary canals of the femur and tibia. Then, the proximal surfaces of the tibia and the distal surfaces of the femur are prepared for receiving the implants. Trial reduction usually follows to assess bone preparation and to select properly sized and configured tibial and femoral implants. The actual tibial and femoral implants are then assembled and implanted into the knee.

The tibial and femoral canals are not always aligned with, but rather are generally offset parallel a distance from, the mechanical axis of the leg. Because of such parallel offset, when a stem is inserted into an offset canal, the attached load bearing component is not aligned with, but rather is offset from, the mechanical axis of the leg. To accommodate for such offset canals, some stems, such as those disclosed in U.S. Patent No. 5,290,313 to Heldreth and PCT Application No. WO 00/06056, are formed with two longitudinal axes offset from each other so that one axis runs through the center of the tibial or femoral load bearing component and the other axis is aligned with the offset tibial or femoral canal. In this way, when a stem is inserted into a canal offset from the mechanical axis of the leg, the longitudinal axis of the load bearing component may still be aligned with the mechanical axis of the leg. Although offset, the axes of such stems, however, are still parallel to each other.

While the stem may connect directly to the tibial or femoral load bearing component, intermediate stem extensions, such as those disclosed in U.S. Patent No. 5,782,920 to Colleran, have been used to connect the stems and components. Colleran discloses a tibial prosthesis that includes a tibial tray, a stem, and a stem extension that connects the stem to the tibial tray. In

contrast to the Heldreth-type stems with offset longitudinal axes, the stem in Colleran has, like most stems, a single longitudinal axis. The Colleran stem extension, rather than the actual stem, is the component which features offset longitudinal axes. When the system is assembled, the desired parallel offset between the stem and the tibial tray is obtained by virtue of the stem extension. Again, however, the axis of the stem is parallel to the axis of the tibial tray and to the mechanical axis of the leg.

Studies have shown, however, that in addition to being offset from the mechanical axis, the tibial and femoral canals are not always disposed parallel to the mechanical axis of the leg. Rather, across a population of humans, a valgus bowing of the tibia exists from about 1.63° +/- 1.57° relative to the mechanical axis. Consequently, if a stem oriented parallel to the mechanical axis is inserted into the bowed tibial canal, the stem can impinge on the lateral cortex of the tibial canal proximal to the knee and the medial cortex distal to the knee. Similarly, the femoral canal can bow posteriorly relative to the mechanical axis, which results in impingement by the stem of the anterior cortex of the femoral canal in the diaphysis of the femur and the posterior cortex slightly superior to the knee. Such impingement can prevent adequate penetration of the canal by the stem and result in improper positioning of the tibial and femoral components in the knee.

Improper positioning of the component with respect to the bone can have grave effects, including stress shielding and bone loss due to nonuniform transfer of load from the bone to the stem, and can also limit range of motion. Insertion of a stem into an angled tibial canal may result in the misalignment of the tibial component with the tibial plateau so that a part of the tibial component hangs over the tibial plateau. Such overhang can lead to the tibial component rubbing the soft tissue surrounding the knee, causing irritation and pain. Moreover, a consequence of overhang by one side of the tibial component is underhang by the other side of the tibial component, so

that the underhang portion of the component is resting on the softer cancellous bone instead of the harder cortical bone along the peripheral rim of the tibial plateau. The component consequently may sink into the softer bone, causing the entire component to tilt toward the side of underhang. This can jeopardize the stability of the implant.

Furthermore, the orientation of the femoral canal is such that when the stem and connected femoral cutting block is inserted, the femoral resection may notch the anterior cortex, predisposing the femur to fracture. More often, however, the orientation of the canal forces the femoral component's anterior flange to sit proud on the anterior cortex, thereby creating a gap between the anterior flange of the component and the anterior cortex of the femur. Traditionally the gap has been filled with bone cement, bone graft, or a metal shim or augment. This step of filling the gap adds time to the procedure.

To prevent such adverse effects by better positioning the stem into the bowed canal, surgeons often will select a smaller diameter stem that can be inserted the requisite distance into the canal without impinging the bone unduly or in undesired places. However, use of a smaller diameter stem compromises the fit between the stem and the canal, which can lead to movement of the stem within the canal. Such movement can result in undesired shifting of the attached load bearing component relative to the bone so that the component is located in an undesirable position within the knee. It can also result in instability of the prosthesis in general, excess wear, and other adverse effects.

Surgeons who choose not to downsize the diameter of the stem sometimes, perhaps unknowingly, rotate the femoral or tibial load bearing component and the attached stem to orient the stem relative to the canal to permit deeper penetration of the canal by the stem. This can also result in undesirable positioning of the load bearing component and consequent effects such as those disclosed above.

Summary of the Invention

The present invention addresses the issues discussed above by providing an intermediate stem extension that angularly orients an attached tibial or femoral implant stem relative to its corresponding load bearing component (e.g., tibial tray, condylar component) to facilitate positioning of the stem in a bowed or angled tibial or femoral canal in a manner that allows closer correspondence between the geometry of the implant components and the geometry of the tibia, femur, and knee, and better alignment of the load bearing components with the mechanical axis of the leg.

The extension includes a female taper that engages the tibial and/or femoral load bearing component so that the longitudinal axis of the female taper is aligned with the longitudinal axis of the load bearing component (which, when implanted into the knee, should also be aligned with the mechanical axes of the leg). The extension also includes a male taper having a longitudinal axis oriented at an angle relative to the female taper's longitudinal axis. Engagement of the male taper with the stem thereby orients the stem at an angle relative to the female taper's and the load bearing component's aligned longitudinal axes. This angulation of the stem facilitates insertion of the stem into a tibial or femoral canal that is angled relative to the mechanical axis of the leg, while still promoting the desired alignment of the longitudinal axis of the load bearing component with the mechanical axis of the leg. Such angled orientation of the stem compensates for the contour and/or angulation of the canal and facilitates positioning of the stem into the canal in a manner that allows closer correspondence between the geometry of the implant components and the geometry of the tibia, femur, and knee. In addition to having an angled orientation, the male taper may also be offset parallel from the female taper to facilitate positioning of the stem in canals that are not only angled relative to, but also offset parallel from, the mechanical axis of the leg.

According to the present invention, there is provided a tibial implant comprising:

a. a stem adapted to be fitted into a tibial canal;

b. a load bearing component having a longitudinal axis and adapted to approximate the size and shape of a tibial plateau; and

c. an intermediate stem extension for operatively connecting the stem to the load bearing component, wherein the extension is adapted to apply angular orientation in a manner that causes the load bearing component to be positioned within a leg in a manner wherein the longitudinal axis of the load bearing component is substantially aligned with the mechanical axis of the leg.

According to the present invention, there is provided a femoral implant comprising:

a. a stem adapted to be fitted into a femoral canal;

b. a load bearing component having a longitudinal axis and adapted to approximate the size and shape of condyles of a femur; and

c. an intermediate stem extension for operatively connecting the stem to the load bearing component, wherein the extension is adapted to apply an angular orientation in a manner that causes the load bearing component to be positioned within a leg in a manner wherein the longitudinal axis of the load bearing component is substantially aligned with the mechanical axis of the leg.

According to the present invention, there is provided a knee implant system comprising:

a. a tibial stem adapted to be fitted into a tibial canal;

b. a tibial load bearing component adapted to approximate the size and shape of a tibial plateau;

c. an tibial intermediate stem extension for operatively connecting the tibial stem to the tibial load bearing component, the extension comprising

a central body having a female taper and a male taper, wherein the female taper has a longitudinal axis and the male taper has a longitudinal axis disposed at an angle relative to the longitudinal axis of the female taper;

d. a femoral stem adapted to be fitted into a femoral canal; and

e. a femoral load bearing component adapted to approximate the size and shape of condyles of a femur.

According to the present invention, there is provided a method of installing a knee implant comprising:

a. preparing a proximal portion of the tibia and tibial canal of a patient;

b. preparing a distal portion of the femur and femoral canal of the patient;

c. performing trial reduction in order to select a tibial implant and a femoral implant for the tibia and femur, respectively;

d. introducing the tibial implant into the tibial canal, the tibial implant comprising:

a tibial stem adapted to be fitted into a tibial canal;

a tibial load bearing component adapted to approximate the size and shape of a tibial plateau; and

an tibial intermediate stem extension for operatively connecting the tibial stem to the tibial load bearing component, the extension comprising a central body having a female taper and a male taper, wherein the female taper has a longitudinal axis and the male taper has a longitudinal axis disposed at an angle relative to the longitudinal axis of the female taper; and

e. introducing the femoral implant into the femoral canal, the femoral implant comprising:

a femoral stem adapted to be fitted into a femoral canal; and

a femoral load bearing component adapted to approximate the size and shape of condyles of a femur and operatively connect with the femoral stem.

According to the present invention, there is provided a prosthesis kit for replacement of a knee, comprising:

a. a stem adapted to be fitted into a tibial canal;

b. a load bearing component adapted to approximate the size and shape of a tibial plateau; and

c. a plurality of intermediate stem extensions of which one may be selected to connect the stem to the load bearing component, each intermediate stem extension comprising a central body comprising:

a female taper having a longitudinal axis;

a male taper having a longitudinal axis, wherein the longitudinal axis of the male taper is disposed at an angle relative to the longitudinal axis of the female taper and offset parallel a first distance from the longitudinal axis of the female taper at a second distance from a bottom of the female taper.

According to the present invention, there is provided a prosthesis kit for replacement of a knee, comprising:

a. a stem adapted to be fitted into a femoral canal;

b. a load bearing component adapted to approximate the size and shape of condyles of a femur; and

c. a plurality of intermediate stem extensions of which one may be selected to connect the stem to the load bearing component, each intermediate stem extension comprising a central body comprising:

a female taper having a longitudinal axis;

a male taper having a longitudinal axis, wherein the longitudinal axis of the male taper is disposed at an angle relative to the longitudinal axis of the female taper and offset parallel a first distance from the longitudinal

axis of the female taper at a second distance from a bottom of the female taper.

It is an object of the present invention to provide an implant stem extension which facilitates positioning of an implant stem in a tibial and/or femoral canal in a manner that allows closer correspondence between the geometry of the implant components and the geometry of the tibia, femur, and knee.

It is another object of the present invention to provide an implant stem extension which facilitates positioning of an implant stem in a tibial and/or femoral canal in a manner that promotes alignment of the longitudinal axis of a load bearing component with the mechanical axis of the leg.

It is yet another object of the present invention to provide an implant stem extension which improves the fit between a tibial or femoral stem and a tibial and/or femoral canal, respectively, and thereby stabilizes the implant in the knee.

It is still another object of the present invention to provide a stem extension that minimizes undue impingement by the stem within the intramedullary cortex of the tibia and/or femur and consequent effects.

Other objects, features, and advantages of the present invention will be apparent with respect to the remainder of this document.

Brief Description of the Drawings

FIG. 1 is a perspective view of one embodiment of the tibial implant of the present invention.

FIG. 2 is a perspective view of one embodiment of the femoral implant of the present invention.

FIG. 3 is a side cross-sectional view of a knee illustrating an implanted tibial and femoral implant, both having the stem extension according to the present invention.

FIG. 4 is a perspective view of one embodiment of the stem extension of the present invention.

FIG. 5 is a cross-section taken along line 5-5 in FIG. 4.

FIG. 6 is a cross-section taken along line 6-6 in FIG. 4.

FIG. 7 is a cross-section taken along line 7-7 in FIG. 4.

FIG. 8 is a cross-section taken along line 8-8 in FIG. 4.

FIG. 9 is a perspective view of another embodiment of the stem extension of the present invention.

FIG. 10 is a cross-section taken along line 10-10 in FIG. 9.

FIG. 11 is a cross-section taken along line 11-11 in FIG. 9.

FIG. 12 is a front cross-sectional view of a knee illustrating an implanted tibial and femoral implant, both having the stem extension according to the present invention.

Detailed Description of the Drawings

FIG. 1 illustrates an embodiment of a tibial implant 10 according to the present invention. Tibial implant 10 comprises a tibial load bearing component 12 (ex. tibial tray or platform), a stem 14, and a stem extension 16. The extension 16 connects the tibial load bearing component 12 and the stem 14. Similarly, FIG. 2 illustrates an embodiment of a femoral implant 18 according to the present invention, comprising a femoral load bearing component 20 (ex. condylar component) and a stem 14. The femoral implant 18 may also include a stem extension 16 connecting the femoral load bearing component 20 and the stem 14 (as shown in FIG. 2). FIG. 3 shows a tibia 38 and femur 40 into which a tibial implant 10 and femoral implant 18 have been implanted. While not necessary, a stem extension 16 has been used in both the tibial implant 10 and the femoral implant 18 to connect the stems 14 to their respective tibial and femoral load bearing components 12, 20.

FIGS. 4-8 illustrate one embodiment of the stem extension 16. The extension 16 may be made from a variety of materials possessing suitable

physical properties including structural integrity and adequate strength, but is preferably made from an alloy, such as titanium (Ti-6Al-4V) or cobalt chromium (CoCr).

The extension 16 has a central body 22 with a female taper 24 and a male taper 26. The male taper 26 may be, but does not have to be, integrally-formed with the central body 22. The female taper 24 couples with the load bearing component 12, 20 and the male taper 26 couples with the stem 14 (see FIGS. 1-3). Note, however, that in an alternative embodiment, this configuration could be reversed, i.e. the male taper 26 could couple with the load bearing component 12, 20 and the female taper 24 could couple with the stem 14.

The exterior of the male taper 26 and the interior of the female taper 24 are preferably Morse tapers, having generally circular cross sections (see FIGS. 6 and 7). The circular cross-section of the tapers 24, 26 facilitates rotation and other adjustment of the stem extension 16 relative to the load bearing component 12, 20 and/or the stem 14 to better position the stem 14 within the canal. The walls of the tapers 24, 26 stabilize the stem extension 16 relative to the load bearing component 12, 20 and/or the stem 14 when the desired position is attained. Note, however, that the female and male taper 24, 26 may be any shape or combination of shapes appropriate to couple with the stem 14 and the load bearing component 12, 20. Moreover, the cross-sections of the female and male taper 24, 26 in a single extension 16 may be of different shapes. Additionally, the area of the cross-sections of the tapers 24, 26 may remain constant or vary along the length of the extension 16, depending on the shape of the parts to which they will mate on the load bearing component 12, 20 and the stem 14.

The central body 22 may assume a variety of shapes as well. In the embodiment shown in FIGS. 4-8, the central body 22 is oval-shaped (see

FIG. 8). In an alternative embodiment shown in FIGS. 9-11, the central body is circular-shaped (see FIG. 11).

The female and male tapers 24, 26 are oriented angularly relative to each other. Longitudinal axes 28, 30 run through the center of the female taper 24 and the male taper 26, respectively, in a manner to form the center of rotation of each of the tapers. The longitudinal axes 28, 30 are not parallel. The angular orientation, expressed in degrees, represents the angle (α) between the longitudinal axes 28, 30 of the female and male tapers 24, 26.

Moreover, the female and male tapers 24, 26 are preferably, but do not have to be, offset from each other. The parallel offset (x), expressed in millimeters, represents the distance between the longitudinal axis 28 of the female taper 24 and the longitudinal axis 30 of the male taper 26 at a certain distance (D) from the bottom 36 of the female taper 24.

Because the desired parallel offset and angular orientation will vary depending on the patient, preferred values for x and α could vary. However, studies and experimentation have revealed that the parallel offset (x) is preferably between 1 and 15 millimeters at a distance (D) between 1 and 100 mm, but preferably at a distance (D) between 10 and 50 mm. Moreover, the angular orientation (α) is preferably between 1° and 10°. Stem extensions 16 may be offered with different permutations of parallel offsets and angles.

When the female taper 24 engages the load bearing component 12, 20, the longitudinal axis 28 of the female taper 24 is aligned with both the longitudinal axis of the load bearing component 12, 20 and with the mechanical axis of the leg 34 (see FIG. 12). The longitudinal axis 30 of the male taper 26, and consequently the longitudinal axis of the stem 14 mounted onto the male taper 26, is angled relative to the mechanical axis of the leg. When the stem 14 is inserted into a canal, its angled orientation allows it to better follow and fit within the angled or bowed contour of the canal, thereby

significantly reducing or eliminating undue impingement by the stem 14 on the canal without compromising (and even facilitating) the fit between the stem 14 and the canal and the overall stability of the implant. The angled stem also facilitates the desired alignment between the load bearing component 12, 20 and the mechanical axis of the leg.

In addition to being angled relative to the mechanical axis of the leg, the longitudinal axis 30 of the male taper 26, and consequently the longitudinal axis of the stem 14 mounted onto the male taper 26, may also be offset from the mechanical axis of the leg. The stem 14 can therefore be positioned in the canal in a manner that allows closer correspondence between the geometry of the implant components and that facilitates the desired alignment between the load bearing component 12, 20 and the mechanical axis of the leg.

The foregoing is provided for the purpose of illustrating, explaining and describing embodiments of the present invention. Further modifications and adaptations to these embodiments will be apparent to those skilled in the art and may be made without departing from the spirit of the invention or the scope of the following claims.

What is claimed is:

1. A tibial implant comprising:

a. a stem adapted to be fitted into a tibial canal;

b. a load bearing component having a longitudinal axis and adapted to approximate the size and shape of a tibial plateau; and

c. an intermediate stem extension for operatively connecting the stem to the load bearing component, wherein the extension is adapted to apply angular orientation in a manner that causes the load bearing component to be positioned within a leg in a manner wherein the longitudinal axis of the load bearing component is substantially aligned with the mechanical axis of the leg.

2. The tibial implant of claim 1, wherein the stem extension includes a male taper for engaging the stem and a female taper for engaging the load bearing component, wherein, when the implant is so assembled and implanted into the leg, the stem is oriented at an angle to the mechanical axis of the leg.

3. The tibial implant of claim 1, wherein the stem extension is adapted to apply parallel offset in a manner that causes the load bearing component to be positioned within the leg in a manner wherein the longitudinal axis of the load bearing component is substantially aligned with the mechanical axis of the leg.

4. The tibial implant of claim 3, wherein the stem extension includes a male taper for engaging the stem and a female taper for engaging the load bearing component, wherein, when the implant is so assembled and

implanted into the leg, the stem is oriented at an angle to and offset parallel from the mechanical axis of the leg.

5. A femoral implant comprising:

a. a stem adapted to be fitted into a femoral canal;

b. a load bearing component having a longitudinal axis and adapted to approximate the size and shape of condyles of a femur; and

c. an intermediate stem extension for operatively connecting the stem to the load bearing component, wherein the extension is adapted to apply an angular orientation in a manner that causes the load bearing component to be positioned within a leg in a manner wherein the longitudinal axis of the load bearing component is substantially aligned with the mechanical axis of the leg.

6. The femoral implant of claim 5, wherein the stem extension includes a male taper for engaging the stem and a female taper for engaging the load bearing component, wherein, when the implant is so assembled and implanted into the leg, the stem is oriented at an angle to the mechanical axis of the leg.

7. The femoral implant of claim 5, wherein the stem extension is adapted to apply parallel offset in a manner that causes the load bearing component to be positioned within a leg in a manner wherein the longitudinal axis of the load bearing component is substantially aligned with the mechanical axis of the leg.

8. The femoral implant of claim 7, wherein the stem extension includes a male taper for engaging the stem and a female taper for engaging the load bearing component, wherein, when the implant is so assembled and

implanted into the leg, the stem is oriented at an angle to and offset parallel from the mechanical axis of the leg.

9. The tibial implant of claim 1, wherein the extension comprises a central body having a female taper and a male taper, wherein the female taper has a longitudinal axis and the male taper has a longitudinal axis disposed at an angle relative to the longitudinal axis of the female taper.

10. The tibial implant of claim 9, wherein the angle is at least about 1°.

11. The tibial implant of claim 10, wherein the angle is no more than about 10°.

12. The tibial implant of claim 9, wherein the longitudinal axis of the male taper is offset parallel a first distance from the longitudinal axis of the female taper at a second distance from a bottom of the female taper.

13. The tibial implant of claim 12, wherein the first distance is between 1 millimeter and 15 millimeters when the second distance is between 1 and 100 millimeters.

14. The tibial implant of claim 13, wherein the first distance is between 1 millimeter and 10 millimeters when the second distance is between 10 and 50 millimeters.

15. The tibial implant of claim 12, wherein the first distance is approximately zero when the second distance is between 1 and 100 millimeters.

16. The tibial implant of claim 9, wherein a cross-section of the female taper and a cross-section of the male taper are substantially different shapes.

17. The tibial implant of claim 9, wherein a cross-section of the female taper and a cross-section of the male taper are the substantially identical shape.

18. The tibial implant of claim 17, wherein the shape is substantially circular.

19. The tibial implant of claim 9, wherein the cross-sectional area of the female taper and the cross-sectional area of the male taper vary along the length of the extension.

20. The tibial implant of claim 9, wherein the cross-sectional area of the female taper and the cross-sectional area of the male taper remain substantially constant along the length of the extension.

21. The tibial implant of claim 9, wherein the female taper operatively engages the load bearing component and the male taper operatively engages the stem.

22. The tibial implant of claim 9, wherein the male taper operatively engages the load bearing component and the female taper operatively engages the stem.

23. The tibial implant of claim 9, wherein the extension comprises an alloy.

24. The tibial implant of claim 23, wherein the alloy is titanium.

25. The tibial implant of claim 9, wherein the male taper is integrally-formed with the central body.

26. The femoral implant of claim 5, wherein the extension comprises a central body having a female taper and a male taper, wherein the female taper has a longitudinal axis and the male taper has a longitudinal axis disposed at an angle relative to the longitudinal axis of the female taper.

27. The femoral implant of claim 26, wherein the male taper is integrally-formed with the central body.

28. The femoral implant of claim 26, wherein the angle is at least about 1°.

29. The femoral implant of claim 28, wherein the angle is no more than about 10°.

30. The femoral implant of claim 26, wherein the longitudinal axis of the male taper is offset parallel a first distance from the longitudinal axis of the female taper at a second distance from a bottom of the female taper.

31. The femoral implant of claim 30, wherein the first distance is between 1 millimeter and 15 millimeters when the second distance is between 1 and 100 millimeters.

32. The femoral implant of claim 31, wherein the first distance is between 1 millimeter and 10 millimeters when the second distance is between 10 and 50 millimeters.

33. The femoral implant of claim 30, wherein the first distance is approximately zero when the second distance is between 1 and 100 millimeters.

34. The femoral implant of claim 26, wherein a cross-section of the female taper and a cross-section of the male taper are substantially different shapes.

35. The femoral implant of claim 26, wherein a cross-section of the female taper and a cross-section of the male taper are the substantially identical shape.

36. The femoral implant of claim 35, wherein the shape is substantially circular.

37. The femoral implant of claim 26, wherein the cross-sectional area of the female taper and the cross-sectional area of the male taper vary along the length of the extension.

38. The femoral implant of claim 26, wherein the cross-sectional area of the female taper and the cross-sectional area of the male taper remain substantially constant along the length of the extension.

39. The femoral implant of claim 26, wherein the female taper operatively engages the load bearing component and the male taper operatively engages the stem.

40. The femoral implant of claim 26, wherein the male taper operatively engages the load bearing component and the female taper operatively engages the stem.

41. The femoral implant of claim 26, wherein the extension comprises an alloy.

42. The femoral implant of claim 41, wherein the alloy is titanium.

43. A knee implant system comprising:

a. a tibial stem adapted to be fitted into a tibial canal;

b. a tibial load bearing component adapted to approximate the size and shape of a tibial plateau;

c. an tibial intermediate stem extension for operatively connecting the tibial stem to the tibial load bearing component, the extension comprising a central body having a female taper and a male taper, wherein the female taper has a longitudinal axis and the male taper has a longitudinal axis disposed at an angle relative to the longitudinal axis of the female taper;

d. a femoral stem adapted to be fitted into a femoral canal; and

e. a femoral load bearing component adapted to approximate the size and shape of condyles of a femur.

44. The knee implant system of claim 43, wherein the male taper of the tibial intermediate stem extension is integrally-formed with the central body of the tibial intermediate stem extension.

45. The knee implant system of claim 43, wherein the longitudinal axis of the male taper is offset parallel a first distance from the longitudinal axis of the female taper at a second distance from a bottom of the female taper.

46. The knee implant system of claim 43, further comprising a femoral intermediate stem extension for operatively connecting the femoral stem to the femoral load bearing component, the extension comprising a central body

having a female taper and a male taper, wherein the female taper has a longitudinal axis and the male taper has a longitudinal axis disposed at an angle relative to the longitudinal axis of the female taper.

47. The knee implant system of claim 46, wherein the male taper of the femoral intermediate stem extension is integrally-formed with the central body of the femoral intermediate stem extension.

48. The knee implant system of claim 46, wherein the longitudinal axis of the male taper of the tibial stem extension is offset parallel a first distance from the longitudinal axis of the female taper of the tibial stem extension at a second distance from a bottom of the female taper of the tibial stem extension, and the longitudinal axis of the male taper of the femoral stem extension is offset parallel a third distance from the longitudinal axis of the female taper of the femoral stem extension at a fourth distance from a bottom of the female taper of the femoral stem extension.

49. The knee implant system of claim 48, wherein the first and third distances are between 1 and 15 millimeters when the second and fourth distances are between 1 and 100 millimeters.

50. A method of installing a knee implant comprising:

a. preparing a proximal portion of the tibia and tibial canal of a patient;

b. preparing a distal portion of the femur and femoral canal of the patient;

c. performing trial reduction in order to select a tibial implant and a femoral implant for the tibia and femur, respectively;

d. introducing the tibial implant into the tibial canal, the tibial implant comprising:

a tibial stem adapted to be fitted into a tibial canal;

a tibial load bearing component adapted to approximate the size and shape of a tibial plateau; and

an tibial intermediate stem extension for operatively connecting the tibial stem to the tibial load bearing component, the extension comprising a central body having a female taper and a male taper, wherein the female taper has a longitudinal axis and the male taper has a longitudinal axis disposed at an angle relative to the longitudinal axis of the female taper; and

e. introducing the femoral implant into the femoral canal, the femoral implant comprising:

a femoral stem adapted to be fitted into a femoral canal; and

a femoral load bearing component adapted to approximate the size and shape of condyles of a femur and operatively connect with the femoral stem.

51. The method of claim 50, wherein the male taper of the tibial intermediate stem extension is integrally-formed with the central body of the tibial intermediate stem extension.

52. The method of claim 50, wherein the femoral implant further comprises a femoral intermediate stem extension for operatively connecting the femoral stem to the femoral load bearing component, the extension comprising a central body having a female taper and a male taper, wherein the female taper has a longitudinal axis and the male taper has a longitudinal axis disposed at an angle relative to the longitudinal axis of the female taper.

53. The method of claim 52, wherein the male taper of the femoral intermediate stem extension is integrally-formed with the central body of the femoral intermediate stem extension.

54. The method of claim 52, wherein the longitudinal axis of the male taper of the tibial stem extension is offset parallel a first distance from the longitudinal axis of the female taper of the tibial stem extension at a second distance from a bottom of the female taper of the tibial stem extension, and the longitudinal axis of the male taper of the femoral stem extension is offset parallel a third distance from the longitudinal axis of the female taper of the femoral stem extension at a fourth distance from a bottom of the female taper of the femoral stem extension.

55. A prosthesis kit for replacement of a knee, comprising:

a. a stem adapted to be fitted into a tibial canal;

b. a load bearing component adapted to approximate the size and shape of a tibial plateau; and

c. a plurality of intermediate stem extensions of which one may be selected to connect the stem to the load bearing component, each intermediate stem extension comprising a central body comprising:

a female taper having a longitudinal axis;

a male taper having a longitudinal axis, wherein the longitudinal axis of the male taper is disposed at an angle relative to the longitudinal axis of the female taper and offset parallel a first distance from the longitudinal axis of the female taper at a second distance from a bottom of the female taper.

56. The kit of claim 55, wherein in at least one intermediate stem extension the angle is between 1° and 10° and the first distance is between 1 millimeter

and 15 millimeters when the second distance is between 1 and 100 millimeters.

57. A prosthesis kit for replacement of a knee, comprising:

a. a stem adapted to be fitted into a femoral canal;

b. a load bearing component adapted to approximate the size and shape of condyles of a femur; and

c. a plurality of intermediate stem extensions of which one may be selected to connect the stem to the load bearing component, each intermediate stem extension comprising a central body comprising:

a female taper having a longitudinal axis;

a male taper having a longitudinal axis, wherein the longitudinal axis of the male taper is disposed at an angle relative to the longitudinal axis of the female taper and offset parallel a first distance from the longitudinal axis of the female taper at a second distance from a bottom of the female taper.

58. The kit of claim 57, wherein in at least one intermediate stem extension the angle is between 1° and 10° and the first distance is between 1 millimeter and 15 millimeters when the second distance is between 1 and 100 millimeters.

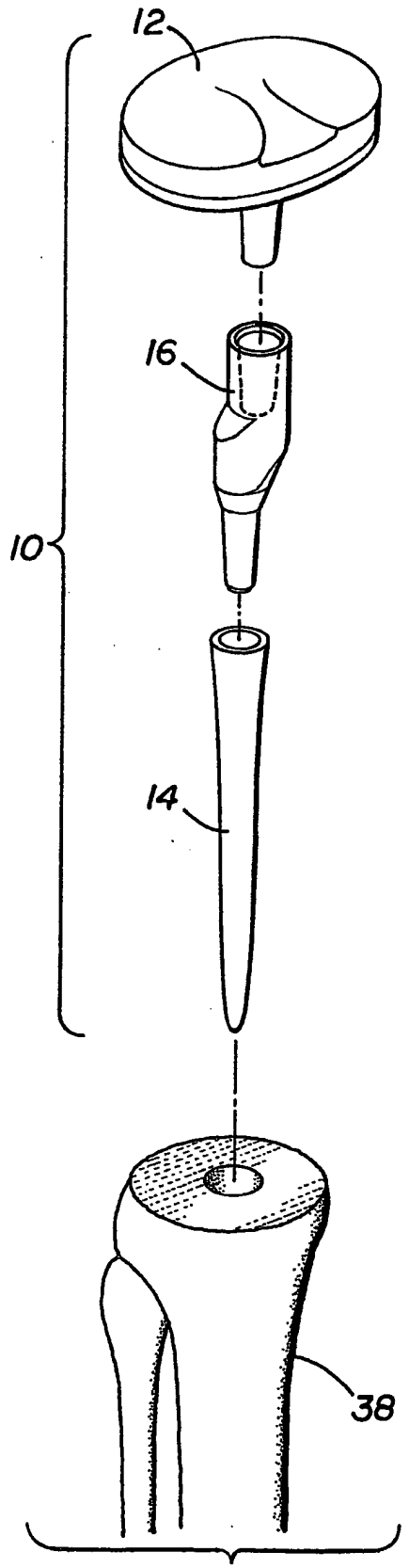

FIG 1

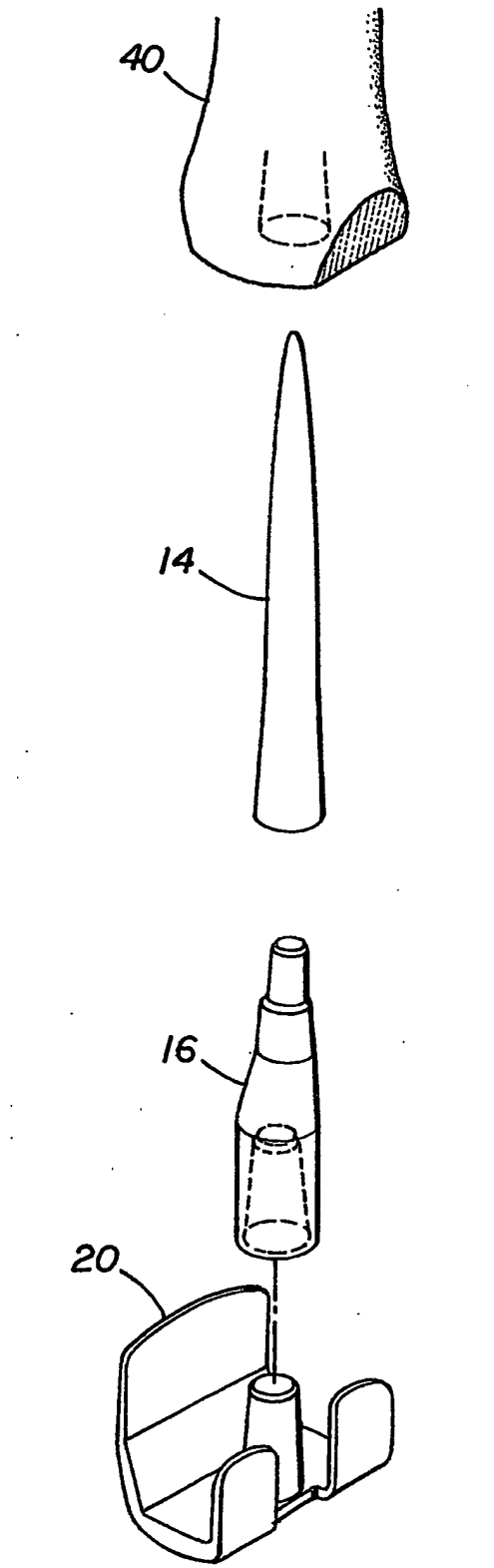

FIG 2

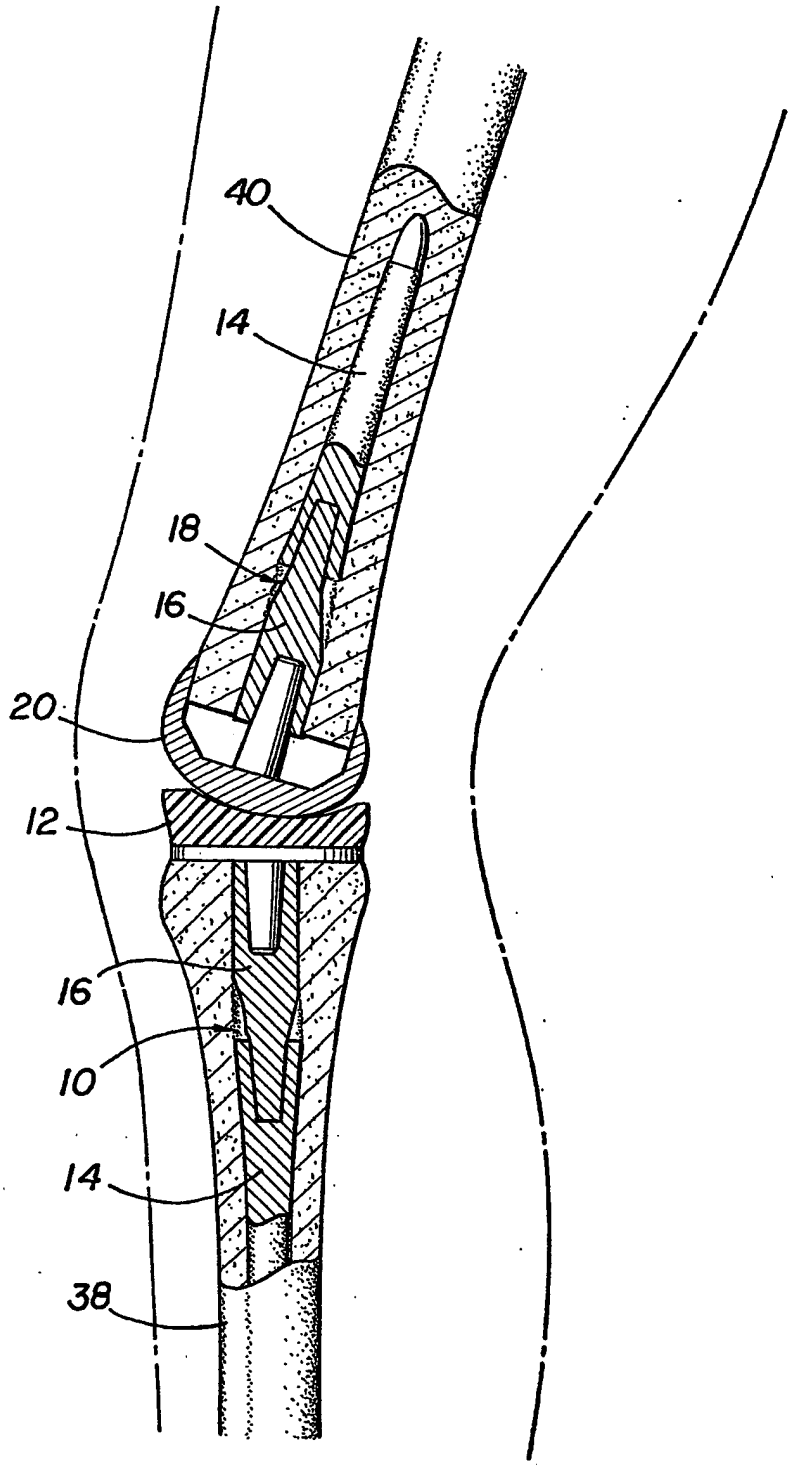

FIG 3

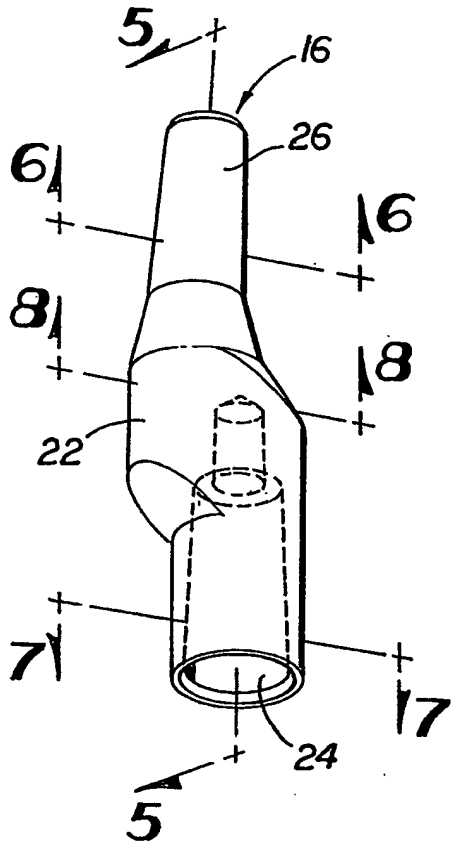

FIG 4

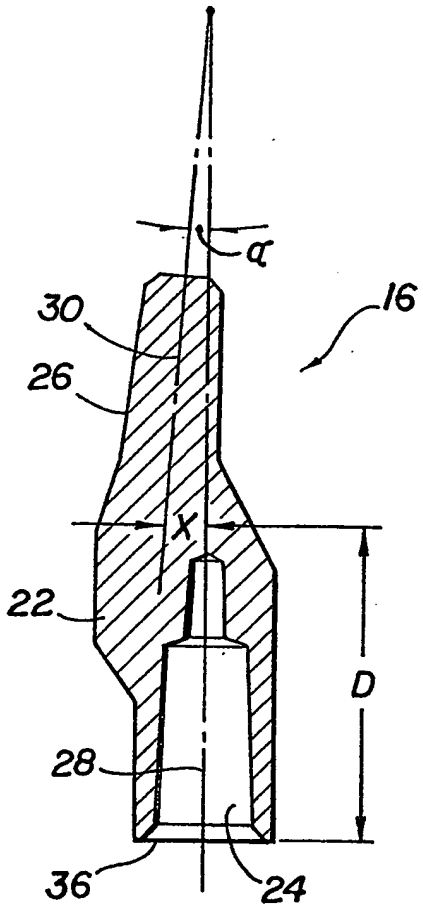

FIG 5

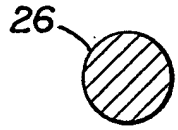

FIG 6

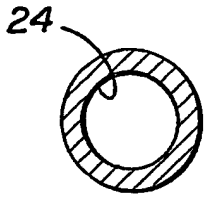

FIG 7

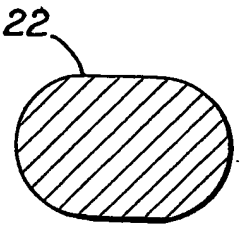

FIG 8

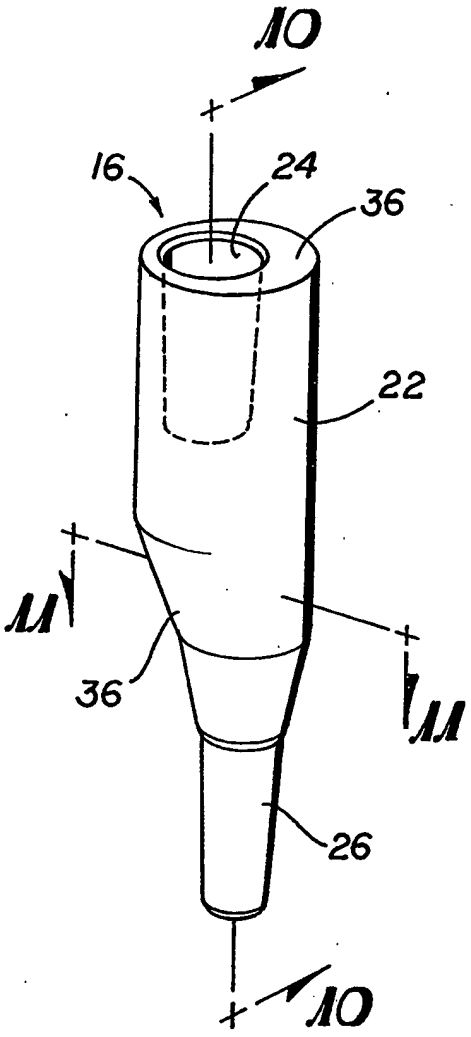

FIG 9

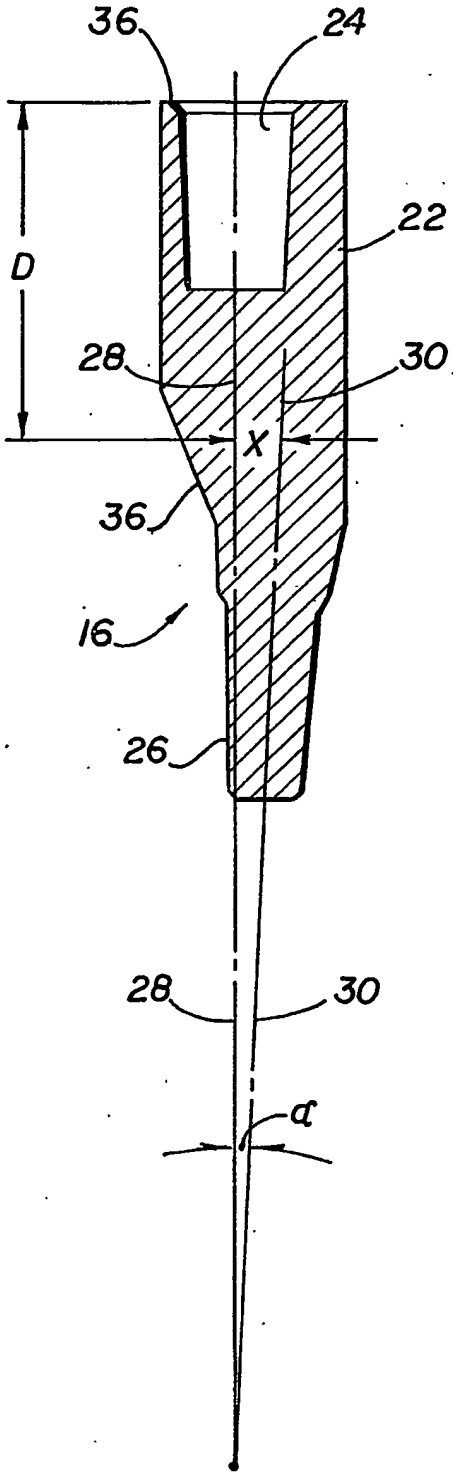

FIG 10

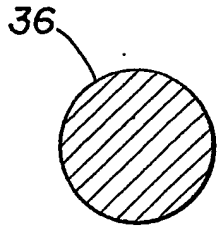

FIG 11

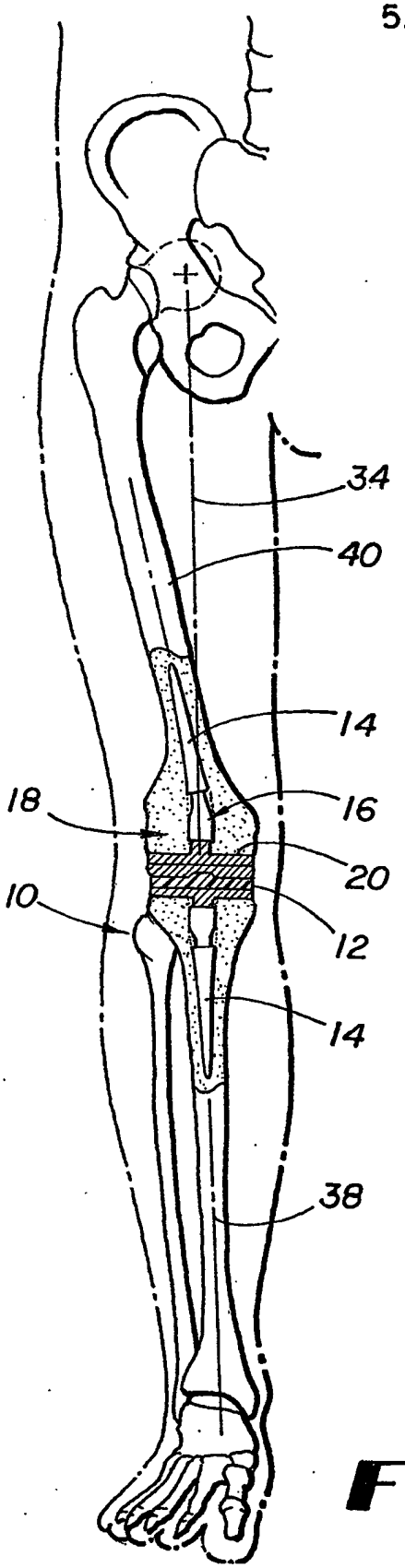

FIG 12

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 01/22724

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/38

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 171 342 B1 (CIPOLLETTI GEORGE B ET AL) 9 January 2001 (2001-01-09) column 3, line 16 - line 39 column 17, line 52 -column 18, line 16; figures 17-29	1-49, 55-58
X	US 6 214 052 B1 (BURKINSHAW BRIAN) 10 April 2001 (2001-04-10) column 4, line 52 -column 6, line 10; figures	1-4
X	US 5 133 760 A (PETERSEN THOMAS D ET AL) 28 July 1992 (1992-07-28) claims 1-9; figures 1-9	1,5
A	EP 0 853 930 A (JOHNSON & JOHNSON PROFESSIONAL) 22 July 1998 (1998-07-22) column 5, line 7 - line 44; figures	1-49, 55-58

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 August 2002	02/09/2002

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Villeneuve, J-M

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 01/22724

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 457 222 A (INTRAPLANT AG) 21 November 1991 (1991-11-21)	
A	EP 0 993 813 A (JOHNSON & JOHNSON PROFESSIONAL) 19 April 2000 (2000-04-19)	

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 01/22724

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 50-54
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 01/22724

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